REMARKS

Reconsideration of this application in view of the above amendments and following remarks is requested. After entry of this reply, claims 1-21 and 30-43 are pending in the application. In this Response and Amendment, claims 1, 37 and 38 are amended, and claims 39-43 are added. Claims 22-29 were previously canceled.

In the Office Action dated April 29, 2008, the Examiner rejects claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 under 35 USC § 102(b) as anticipated by Ellinwood, Jr. (U.S. Patent No. 3,923,060); rejects claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 under 35 USC § 102(e) as anticipated by Gelfand (US 2005/0192638); rejects claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 under 35 USC § 102(e) as anticipated by Mann et al. (US Patent No. 6,941,171); rejects claims 2, 5-13, and 18-19 under 35 USC §103(a) as unpatentable over Ellinwood, Jr. (U.S. Patent No. 3,923,060) or Mann et al. (US Patent No. 6,941,171); rejects claims 16 and 34 under 35 USC §103(a) as unpatentable over Ellinwood, Jr. (U.S. Patent No. 3,923,060) or Mann et al. (US Patent No. 6,941,171) in view of Klein et al. (Anesth Anal 2000; 91:1473-1478); and rejects claims 17, 35, and 38 as unpatentable over Mann et al. (US Patent No. 6,941,171) in view of Gerber et al. (U.S. Patent No. 6,360,750).

Claim Rejections – 35 USC § 102

Applicant respectfully traverses all of the Examiner's 35 USC § 102 rejections. Neither Ellinwood Jr. (U.S. Patent No. 3,923,060), Gelfand (US 2005/0192638), nor Mann (US Patent No. 6,941,171), alone, disclose each and every element of the claimed invention.

Ellinwood Jr. (U.S. Patent No. 3,923,060):

Ellinwood Jr. describes a possible application of a medication dispensing device for treatment of painful spinal dorsal nerves through use of an external trigger (Ellinwood Jr., col. 7, lines 15-22). The patient senses pain and activates the external trigger to release medication. The device's internal timing and logic prevents overdose. Since the device of Ellinwood treats painful spinal dorsal nerves through employment of an external trigger, the device is not completely implanted within the patient. This fact also indicates that the device is for short term acute pain control and not for long term pain management.

Accordingly, considering that Ellinwood Jr. fails to disclose each and every element of the claimed invention, including at least the recitations of claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37, Applicant respectfully requests that the Examiner withdraw the 35 USC § 102(b) rejections based on Ellinwood Jr.

Gelfand (US 2005/0192638 and 60/370,190):

Gelfand purportedly describes implanted pump delivery of nerve blocking agents to renal nerves (60/370,180, page. 22, lines 13-21). Gelfand teaches the application for blocking, or partially blocking, renal nerve signals to and from the kidney, not for long term pain management. Gelfand does not disclose a method for long term pain management.

Accordingly, considering that Gelfand fails to disclose each and every element of the claimed invention, including at least the recitations of claims 1, 3-4, 14-15, 20-21, 30-33, and 36-

37, Applicant respectfully requests that the Examiner withdraw the 35 USC § 102(b) rejections based on Ellinwood Jr.

Mann (US Patent No. 6,941,171)

Mann purportedly teaches a method and system for treatment of incontinence, urgency, frequency, and/or pelvic pain. The method in Mann includes stimulating pelvic nerves or tissues through implantation of electrodes on a lead or by catheter adjacent to the pelvic nerves and tissues (Mann, Abstract). Mann, however, does not disclose a method for long term pain management.

Accordingly, considering that Mann fails to disclose each and every element of the claimed invention, including at least the recitations of independent claims 1, 37 and 38, Applicant respectfully requests that the Examiner withdraw the 35 USC § 102(b) rejections based on Mann.

Although the Applicant does not agree with the rejections made by the Examiner, the Applicant amends claims 1, 37 and 38 to more clearly describe the subject matter of the present invention.

Claim Rejections – 35 USC § 103

The Examiner rejects claims 2, 5-13, and 18-19 under 35 USC §103(a) as unpatentable over Ellinwood Jr. or Mann et al. Applicant respectfully traverses the Examiner's claim rejections under 35 U.S.C. §103(a), as Applicant denies that a prima facie case of obviousness

has been established. As previously discussed, neither Ellinwood Jr. nor Mann disclose each and every element of the present invention. It follows that it is not obvious to use the present invention method for long term pain management in a peripheral neural structure. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections with regard to claims 2, 5-13, and 18-19.

The Examiner rejects claims 16 and 34 under 35 USC §103(a) as unpatentable over Ellinwood Jr. or Mann in view of Klein. Applicant respectfully traverses the Examiner's claim rejections under 35 U.S.C. §103(a), as Applicant denies that a prima facie case of obviousness has been established.

With regard to claim 16, Klein describes using an external disposable infusion pump, and medication is delivered using a epidural catheter (Klein, Methods). The pump and epidural catheter of Klein are both outside of the patient's body. Klein also only describes short term post-operation pain control. The longest time of treatment presented in Klein is 48 hours (Klein, Methods), which is in contrast to the long term pain management of at least one week for the present invention. Klein, therefore, in combination of Ellinwood Jr. or Mann does not teach or suggest the present invention.

Claim 34 teaches a medication including approximately between 10-25 mg/day of tetracaine, approximately between 50-100 mcg/day of clonidine, and approximately between 50-100 mcg/day of baclofen. Clonidine is an alpha-2 agonist. Baclofen is an antispasmodic. Neither Klein, Ellinwood Jr., nor Mann describe using these specific drugs, nor do these

references, either alone or in combination, describe or suggest alpha-2 agonists or antispasmodics in a interventional approach for long term pain management.

Accordingly, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. §103(a) rejection of claims 16 and 34.

The Examiner rejects claims 17, 35, and 38 under 35 USC §103(a) as unpatentable over Mann in view of Gerber. Applicant respectfully traverses the rejections, as Applicant denies that a prima facie case of obviousness has been established.

Mann teaches a method and system for treatment of incontinence, urgency, frequency, and/or pelvic pain. The method in Mann includes stimulating pelvic nerves or tissues through implantation of electrodes on a lead or by catheter adjacent to the pelvic nerves and tissues (Mann, Abstract). To achieve the objective of reducing or eliminating the incidence of unintentional episodes of bladder emptying (i.e., incontinence), as well as other dysfunctions of a perineal structure, such as urgency and frequency, it is necessary to stimulate nerve pathways that diminish involuntary bladder contractions, improve closure of the bladder outlet, and/or improve the long-term health of the urinary system (Mann, col. 9, line 62 – col. 10, line 2).

Mann therefore teaches stimulation of a sensory nerve as producing an electrical impulse that is transmitted along the axon into the dorsal horn of the spinal chord, and stimulation of a motor nerve as conveying electrical impulses through its many peripheral branches that supply muscle fibers and that elicit contraction therein (Mann, col. 11, lines 34-42). It is thus clear that Mann refers to stimulation of a nerve as creating an electrical impulse in that nerve (i.e., exciting

the nerve). Mann describes methods of neural stimulation through electrical stimulation with implanted microstimulators, or using one or more stimulating drugs delivered via infusion catheters (Mann, col. 10, line 65 – col. 11, line 18). Mann does not disclose using opiods, antispasmodics, and alpha 2 agonists as the therapeutic agents delivered using an implantable pump. None of the classes of medications taught by the present invention are generally considered as neural stimulating agents.

Gerber describes an improved surgical method for implanting devices that deliver stimulants to the nervous system (Gerber, Abstract). Like Mann, Gerber uses neural stimulation to achieve its therapeutic objectives (Gerber, col. 5, lines 37-40). Antispasmodics are generally described as agents that quite spasm. They are not known as neural stimulating agents.

Gerber mentions antispasmodics when describing medications used in "more conservative treatments" of bladder control problems (Gerber, col. 4, lines 24-28). The "more conservative treatments" stand in contrast with the interventional treatment approach of Mann and Gerber using implantable devices. In other words, the Mann and Gerber approach is not a conservative treatment, and conservative treatments do not use implantable devices.

Further, patients who are suitable for the Gerber method are selected based on their failure to respond to, or their inability to tolerate, conservative therapies, which include antispasmodic agents. It is quite clear, according to Gerber, that use of antispasmodics and use of the Mann or Gerber method cannot be concurrent. Patients who respond to the conservative treatment with antispasmodics do not need to undergo the interventional procedure described by

Gerber. When patients are eligible for the implantation procedure, they would have failed the conservative treatment first. When patients are treated with the Mann and Gerber method, they are treated with electrical microstimulators and stimulating agents delivered through implanted infusion pumps that cause nerve stimulation, but not with antispasmodics. Neither Mann nor Gerber, either alone or in combination, suggests the use of antispasmodics in the interventional approach. In fact, Gerber teaches away from the combination use of antispasmodics and implantable devices. Therefore, Applicant respectfully requests that the Examiner withdraw the 35 USC §103(a) rejections of claims 17, 35, and 38. Although Applicant does not agree with the rejections made by the Examiner, Applicant amends the claims to more clearly describe the claimed subject matter.

Claims Added by this Response and Amendment

Claims 39-43 are added by this Response and Amendment, of which claims 39 and 42 are independent. Claims 40-41 are dependent on claim 39, with claim 43 dependent on claim 42. Claims 39-43 are added to more completely cover certain aspects of Applicant's invention. For reasons detailed above, the recitations of claims 39-43 are patentable over the prior art of record. The added claims find support throughout the specification and the drawings.

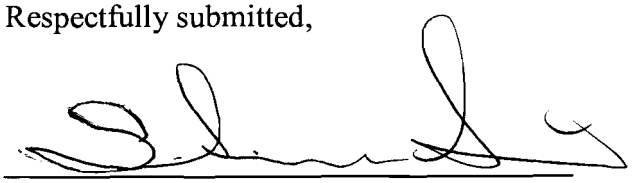
CONCLUSION

In light of the above amendments and remarks, Applicant submits that pending claims 1-21 and 30-43 are allowable, and requests that the Examiner issue an early notice of allowance. The Examiner is invited to call the undersigned attorney to advance prosecution of the application.

If these papers are not considered timely filed, then a Petition is hereby made under 37 C.F.R. § 1.136, and any additional fees required under 37 C.F.R. § 1.136 for any necessary extension of time may be charged to Deposit Account No. 02-2555.

Any fee due is authorized above. Please charge any deficiency or credit any overpayment to BLANK ROME LLP, Deposit Account No. 02-2555 (126066-00101).

Respectfully submitted,



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